DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-882/SCS-017

Pfizer, Inc.
Attention: Manini Patel
Director, Worldwide Regulatory Affairs
235 E. 42nd Street
New York, NY 10017

Dear Ms. Patel:

Please refer to your supplemental new drug application dated October 30, 2003, received October 31, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Neurontin (gabapentin) Tablets.

This supplement provides for the addition of a functional score to the currently marketed Neurontin 600 mg and 800 mg tablets, debossing and a minor change in the dimensions of the tablets.

We acknowledge receipt of your additional submission dated November 24, 2003.

We have completed our review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended. Accordingly, this application is approved, effective on the date of this letter.

We note that the submitted draft labeling includes additional "Changes Being Effected" language contained within the following(b)(4) ---------- (b)(4)---------- The proposed changes cont ained in (b)(4)----------are currently under review and, therefore, we do not consider this approval to apply to them.

Additionally, based on your commitment of April 30, 2004, the following sentences should be included as the second sentence in the DOSAGE AND ADMINISTRATION section, after the sentence, "Neurontin is given orally with or without food."

> Patients should be informed that, should they break the scored 600 or 800 mg tablet in order to administer a half-tablet, they should take the unused half-tablet as the next dose. Half-tablets not used within several days of breaking the scored tablet should be discarded.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-882/S-017." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jacqueline H. Ware, Pharm.D., Senior Regulatory Project Manager, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
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